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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/068,804 05/14/98 MILLER S 00786/292002

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EXAMINER

BASKAR, P

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

10/14/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/068,804

Applicant(s)
Miller I, Samuel

Examiner
Padma Baskar

Group Art Unit
1641



☒ Responsive to communication(s) filed on Aug 2, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-45 is/are pending in the application.

Of the above, claim(s) 19-33 and 35-45 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-18 and 34 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Applicant's election without traverse of Group 1, claims 1-18 and 34 in Paper No. 10 is acknowledged.

2. Claims 19-33 and 35-45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected group. Election was made **without** traverse in Paper No. 10.

3. Claims 1-18 and 34 are now pending.

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected as being vague and indefinite for the recitation of "substantially". It is not clear what substantially pure DNA means? Is it 80% pure or 99% pure?

7. Claim 3 is rejected as being vague and indefinite for the recitation of "degenerate variants". It is not clear what are degenerate variants.

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9. Claim 34 is rejected as being vague and indefinite for the recitation of "high stringency conditions". Applicants have not set forth high stringency conditions in the claims or specification. What are these high stringency conditions? Are these high stringency conditions for all Ssp-encoding DNAs same?

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 17 and 18 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inducing uptake of a bacterial cell by an epithelial cell in vitro assays, does not reasonably provide enablement for inducing uptake of a bacterial cell by an epithelial cell in a mammal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Specification does not disclose a method of inducing uptake of a bacterial cell by an epithelial cell in a mammal comprising expression of the DNA from Salmonella. Furthermore, specification does not teach what that mammal would be. Mammals can be any class of warm blooded higher vertebrates as placentals, marsupials or monotreme including humans, monkeys, mice, and rabbits etc. There are no working examples where a mammal is used for such studies. And also specification does not teach how to administer said cell to said mammal

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12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

13. Claims 1 is rejected under 35 U.S.C. 102~~(a)~~ as being anticipated by THE GENERAL HOSPITAL CORPORATION (WO95/02048).

Claim 1 is directed to a substantially pure DNA encoding a Salmonella secreted protein.

WO 95/02098 discloses that Salmonella secreted protein secretion is dependent on the expression of PrgH gene (pages 5, 11, and 19). The prior anticipates the claimed invention.

14. Claims 1-18 are rejected under 35 U.S.C. 102^a~~(a)~~ as being anticipated by Hueck et al 1995 (Molecular Microbiology 18, 479-490).

Claims are directed to substantially pure DNA encoding a salmonella secreted protein comprises SspB, SspC, SspD and SspA genes, a cell which contains this gene, and a method for uptake of bacterial cell by an epithelial cell.

Hueck et al disclose substantially pure DNA encoding a Salmonella secreted protein, where the DNA comprises SspB, SspC, SspD and SspA genes (page 483, figure 4, page 485 figure 6). Invasion of HEp-2 cells with S.typhimurium discloses a cell which contains the DNA (page 482, 4 th paragraph) because wild-type bacteria inherently contain all these genes. The

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prior art also discloses a method of inducing uptake of a bacterial cell by an epithelial cell by invasion assays (page 488). The prior art anticipates the claimed invention.

15. Claims 1-4, 7, 10 and 16-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Kaniga et al 1995 (Journal of Bacteriology, 177, 3965-3971).

Claims are directed to substantially pure DNA encoding a Salmonella secreted protein comprises SspB, SspC, SspD and SspA genes, a cell which contains this gene, and a method for uptake of bacterial cell by an epithelial cell

Kaniga et al discloses invasion of Salmonella typhimurium in to epithelial cells (material and methods, invasion assays) and secretion of proteins SipB and SipC (page 3948, figure 4 and 5). These proteins are analogous to SspB, SspC. Salmonella typhimurium is an wild type bacteria and hence contain SspB, SspC, SspD and SspA genes. The prior art anticipates the claimed invention. The prior art anticipates the claimed invention.

16. Claims 1-2, 4, 6, 8, 10 and 16-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Hermant et al 1995 (Molecular Microbiology, 17, 781-789).

Claims are directed to substantially pure DNA encoding a salmonella secreted protein comprises SspB, SspC, SspD and SspA genes, a cell which contains this gene, and a method for uptake of bacterial cell by an epithelial cell

Hermant et al discloses Salmonella entry into epithelial cell and the DNA encodes for SspB, SspC, SspD and SspA genes which are analogous to sipEBCDA (pages 781 abstract, Experimental procedures and page 784, figure 2). The prior art anticipates the claimed invention

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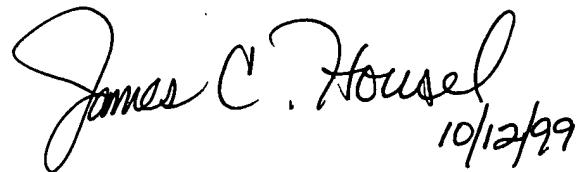
17. No claims are allowed.
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 8:30 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jim Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D

10/8/99

A handwritten signature in black ink that reads "James C. Housel". To the right of the signature, the date "10/12/99" is handwritten.

JAMES C. HOUSEL
SUPERVISORY PATENT EXAMINER